

We claim:

1. A method for the treatment of cancer within a patient, comprising administering to said patient an effective amount of troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours wherein a steady state plasma concentration of troxacitabine of 0.03 to 2.0 μM is achieved during the administration.

2. A method according to claim 1, wherein said cancer is lung cancer, prostate cancer, bladder cancer, colorectal cancer, pancreatic cancer, renal cancer, hepatoma, gastric cancer, breast cancer, ovarian cancer, soft tissue sarcoma, osteosarcoma, hepatocellular carcinoma, skin cancer, leukemia or lymphomas.

3. A method according to claim 2, wherein said cancer is pancreatic cancer.

4. A method according to claim 1, wherein said cancer is acute myelogenous leukemia, chronic myelogenous leukemia, chronic myelogenous leukemia in blastic phase, or refractory myelodysplastic syndromes.

5. A method according to claim 4, wherein said cancer is acute myelogenous leukemia.

6. A method according to claim 2, wherein a steady state plasma concentration of 0.05 to 0.1 μM is achieved during the administration.

7. A method according to claim 4, wherein a steady state plasma concentration of 0.1 to 0.42 μM is achieved during the administration.

8. A method for the treatment of cancer within a patient, comprising administering to said patient an effective amount of troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours, wherein the maximum plasma concentration achieved during the administration is 0.03 to 2.0 μM .

9. A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is below 1.0 μM .

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10. A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is below 0.5 μM .

11. A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is below 0.42 μM .

12. A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is below 0.1 μM .

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13. A method for the treatment of cancer within a patient, comprising administering to said patient troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours at a dose of 0.72 to 12.5 $\text{mg}/\text{m}^2/\text{day}$.

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14. A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 1.0 to 11.0 $\text{mg}/\text{m}^2/\text{day}$.

15. A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 8.0 to 11.0 $\text{mg}/\text{m}^2/\text{day}$.

16. A method according to claim 13, wherein said cancer is lung cancer, prostate cancer, bladder cancer, colorectal cancer,

renal cancer, hepatoma, pancreatic cancer, gastric cancer, breast cancer, ovarian cancer, soft tissue sarcoma, osteosarcoma, hepatocellular carcinoma, skin cancer, leukemia or lymphoma.

5 17. A method according to claim 16, wherein said cancer is pancreatic cancer.

18. A method according to claim 13, wherein said cancer is acute myelogenous leukemia, chronic myelogenous leukemia, chronic
10 myelogenous leukemia in blastic phase, or refractory myelodysplastic syndromes.

19. A method according to claim 18, wherein said cancer is acute myelogenous leukemia.

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20. A method according to claim 16, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 3.0 mg/m²/day.

20 21. A method according to claim 13, wherein said cancer is a solid tumor and the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 2.5mg/m²/day.

22. A method according to claim 18, wherein the dosage amount
25 of troxacitabine or a pharmaceutically acceptable salt thereof 9.5 to 10.5mg/m²/day.

23. A method according to any one of the preceding claims, wherein said continuous infusion is administered for a period of 3
30 to 7 days.

24. A method according to any one of the preceding claims, wherein said continuous infusion is administered for a period of 3 days.

25. A method according to any one of claims 1 to 23, wherein said continuous infusion is administered for a period of 4 days.

5 26. A method according to any one of claims 1 to 23, wherein said continuous infusion is administered for a period of 5 days.

27. A method according to any one of claims 1 to 23, wherein said continuous infusion is administered for a period of 6 days.

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28. A method according to any one of claims 1 to 23, wherein said continuous infusion is administered for a period of 7 days.

29. A method according to claim 16, wherein the dosage amount
15 of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 2.5mg/m²/day, said period is 3 days, and a steady state plasma concentration of 0.05 to 0.1 μM of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

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30. A method according to claim 16, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 2.5mg/m²/day, said period is 4 days, and a steady state plasma concentration of 0.05 to 0.1 μM of troxacitabine or a
25 pharmaceutically acceptable salt thereof is achieved during the administration.

31. A method according to claim 18, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is
30 9.5 to 10.5mg/m²/day, said period is 5 days, and a steady state plasma concentration of 0.1 to 0.42 μM of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

32. A method according to claim 18, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 9.5 to 10.5mg/m²/day, said period is 6 days, and a steady state plasma concentration of 0.1 to 0.42 μM of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

33. A method according to any one of the preceding claims, further comprising repeating said continuous infusion at an interval of every 4 weeks.

34. A method according to any one of the preceding claims, further comprising repeating said continuous infusion at an interval of every 3 weeks.

35. A method according to any one of the preceding claims, further comprising repeating said continuous infusion at an interval of every 5 weeks.

36. A method according to any one of the preceding claims, wherein said continuous infusion is by means of continuous intravenous infusion.

37. A method according to any one of the preceding claims, wherein said method further comprising, in combination with said continuous administration of troxacitabine, administering at least one further therapeutic agent selected from the group comprising nucleoside analogues; chemotherapeutic agents; multidrug resistance reversing agents; and biological response modifiers.

38. A method according to claim 37, wherein said at least one further therapeutic agent is a chemotherapeutic agent selected from Asparaginase, Bleomycin, Busulfan, Carmustine, Chlorambucil, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine,

Daunorubicin, Doxorubicin, Etoposide, Fludarabine, Gemcitabine, Gleevec®, Hydroxyurea, Idarubicin, Ifosfamide, Lomustine, Mechlorethamine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitoxantrone, Pentostatin, Procarbazine, 6-Thioguanine, 5 Topotecan, Vinblastine, Vincristine, Dexamethasone, Retinoic acid and Prednisone.

39. A method according to claim 37, wherein said at least one further therapeutic agent is the multidrug resistance reversing 10 agent PSC 833.

40. A method according to claim 37, wherein said at least one further therapeutic agent is a biological response modifier selected from monoclonal antibodies and cytokines.

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41. A method according to claim 37, wherein said at least one further therapeutic agent is a cytokine selected from interferons, interleukins and colony-stimulating factors.

20 42. A method according to claim 37, wherein said at least one further therapeutic agent is a biological response modifier selected from Rituxan, CMA-676, Interferon-alpha recombinant, Interleukin-2, Interleukin-3, Erythropoietin, Epoetin, G-CSF, GM-CSF, Filgrastim, Sargramostim and Thrombopoietin.

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43. A method according to any one of claims 37 to 42 wherein said of troxacitabine or a pharmaceutically acceptable salt thereof and said at least one further therapeutic agent are administered sequentially.

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44. A method according to any one of claims 37 to 42 wherein said of troxacitabine or a pharmaceutically acceptable salt thereof and at least one further therapeutic agent are administered simultaneously.

45. A method according to claim 44 wherein said of
troxacitabine or a pharmaceutically acceptable salt thereof and at
least one further therapeutic agent are administered in separate
5 pharmaceutical formulations.

46. A method according to claim 44 wherein said of
troxacitabine or a pharmaceutically acceptable salt thereof and at
least one further therapeutic agent are administered in combined
10 pharmaceutical formulations.

47. A method for the administration of troxacitabine or a
pharmaceutically acceptable salt thereof in a host having a tumor,
comprising administering an amount of troxacitabine or a
15 pharmaceutically acceptable salt thereof by continuous infusion for
a period of at least 72 hours, wherein said amount is sufficient to
provide tumor reduction.